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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,315	04/16/2004	Hirokazu Sakai	252003US0	7876

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EXAMINER	
DELCOTTO, GREGORY R	
ART UNIT	PAPER NUMBER
1751	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,315	SAKAI ET AL.	
	Examiner	Art Unit	
	Gregory R. Del Cotto	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-8 are pending. Applicant's response filed 7/17/06 have been entered.

Applicant's election with traverse of Group I, claims 1-7, and the amphipathic amide lipid corresponding to formula (1) in the reply filed on 7/17/06 is acknowledged. The traversal is on the ground(s) that a search of all the claims would not constitute a serious burden on the Office. This is not found persuasive because the Examiner maintains that the inventions of Group I and Group II would require a separate search due to their separate classification thereby placing an undue burden on the Examiner. Furthermore, the Examiner asserts that that the amphipathic amide lipids represented by formulas (1)-(4) are patentably distinct species and each would require a separate search due to their separate classification.

The requirement is still deemed proper and is therefore made FINAL.

Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/17/06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al (US 2006/0036046) or Sakai et al (US 2004/0156815).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

'046 teach a hair cleansing composition containing an amphipathic amide lipid, an anionic surfactant, and a silicone. See paras. 4-8. Note that, '046 teach the same lipids as the formula (1) of the instant claims. The anionic surfactants include polyoxyalkylene alkyl ether sulfates having a C10-C18 alkyl group and from 1 to 5 moles of ethylene oxide, etc. Two or more anionic surfactants may be used in combination in amounts from 1 to 50% by weight. See paras. 26-28. Additionally, cationic polymers may be added in amounts of 0.01% to 20% by weight. See para. 37.

The hair cleansing composition has a pH preferably no less than 4.6 and less than 7 when diluted 20 times by weight with water. See para. 39.

'815 teaches hair cleansing compositions containing an amphiphathic amide lipid, an anionic surfactant, and an organic or inorganic acid or a salt thereof, and having a pH of from 1 to 4.5 at 25 degrees Celsius when diluted with water to 20 times the weight. See paras. 4-8. Note that, '046 teach the same lipids as the formula (1) of the instant claims. The anionic surfactants include polyoxyalkylene alkyl ether sulfates having a C10-C18 alkyl group and from 1 to 5 moles of ethylene oxide, etc. Two or more anionic surfactants may be used in combination in amounts from 1 to 50% by weight. See paras. 40-42. Additionally, cationic polymers may be added in amounts of 0.01% to 20% by weight. See para. 51.

Note that, with respect to the mixture of alkyl ether sulfate surfactants as recited by the instant claims, the Examiner asserts that '046 or '815 suggest mixtures of alkyl ether sulfate surfactants as recited by the instant claims.

'046 or '815 do not teach, with sufficient specificity, a composition containing an amphiphatic lipid, an alkyl ether sulfate mixture, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition containing an amphiphatic lipid, an alkyl ether sulfate mixture, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the

broad teachings of '046 or '815 suggest a composition containing an amphiphatic lipid, an alkyl ether sulfate mixture, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO97/35548 in view of EP 1,166,766.

'548 teaches hair conditioning shampoo compositions containing a specific surfactant component comprising an ethoxylated alkyl sulfate surfactant having from about 1 to about 8 moles of ethoxylation and an amphoteric surfactant with insoluble, dispersed, nonionic silicone and a select soluble cellulosic cationic polymer hair conditioning agent. See Abstract. The alkyl ether sulfates contain an alkyl group of from about 8 to about 24 carbon atoms and have 1 to 8 moles of ethoxylated units. Highly preferred alkyl ether sulfates are those comprising a mixture of individual compounds, said mixture having an average alkyl chain length of from about 10 to about 16 carbon atoms and an average degree of ethoxylation of from about 1 to about 4 moles of ethylene oxide. See page 6, lines 1-22.

'548 does not teach the use of an amphiphatic amide lipid or a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

'766 teaches dermatologic preparations capable of exerting excellent effects of maintaining normal barrier functions of the horny layer, restoring and reinforcing damaged barrier functions, heightening water retention of the horny layer and

remedying skin chapping, and novel diamide derivatives having such effects. Suitable diamides include those having the same general formula as formula (1) of the instant claims. The cosmetics may be formulated into various forms such as W/O and O/W emulsion cosmetics such as hair cosmetics including hair conditioners, shampoos, etc. The amide may be used in amounts of 0.01 to 20% by weight. See page 6, lines 45-60. The hair cosmetic may contain surfactants such as anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants including alkyl ether sulfates, etc. These surfactants may be used in amounts from 5 to 30% by weight. See para. 24.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an amphiphatic amide lipid in the composition taught by '548, with a reasonable expectation of success, because '766 teaches the advantageous properties imparted to a similar shampoo composition when using an amphiphatic amide lipid.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '548 in combination with '766 suggest a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and

the other requisite components of the composition in the specific amounts as recited by the instant claims.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,166,766 in view of Sakai et al (US 2006/0036046), WO97/35548, Hoshowski et al (US 5,137,715), or Sakai et al (US 2004/0156815).

'766 is relied upon as set forth above. However, '766 does not teach the use of a mixture of alkyl ether sulfates, a cationic cellulose polymer, or a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, a cationic polymer, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

'046, '548, or '815 are relied upon as set forth above.

Hoshowski et al teach a hair shampoo-conditioner composition including an anionic cleansing surfactants, such as alkyl sulfate or an alkyl ether sulfate, and a polymeric conditioning compound, in a suitable carrier, and having a pH of from about 2.5 to less than 7, to cleanse the hair. See Abstract.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate the composition as taught by '766 at a pH as recited by instant claim 7, with a reasonable expectation of success, because Hoshowski, '046, or '815 teach formulating similar shampoo compositions at a pH as recited by instant claim 7.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a mixture of alkyl ether sulfate surfactants in the

composition taught by '766, with a reasonable expectation of success, because '046, '548, or '815 teaches the use of a mixture of alkyl ether sulfate surfactants in a similar shampoo composition and further, '766 teaches the use of alkyl ether sulfate surfactants in general.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a cationic polymer in the composition taught by '766, with a reasonable expectation of success, because '046, '548, or '815 teaches that cationic polymers server a conditioning agents for hair in a similar shampoo composition and further, '766 teaches the use of various optional ingredients which would encompass cationic polymers.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '766 in combination with '046, '548, '815 and Hoshowski et al suggest a composition having the specific pH containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO97/35548 in view of EP 1,166,766 as applied to claims 1-6 above, and further in

view of Sakai et al (US 2006/0036046), Hoshowski et al (US 5,137,715), or Sakai et al (US 2004/0156815).

'548 or '766 are relied upon as set forth above. However, neither reference teaches the specific pH of the composition as recited by instant claim 7.

'046, Hoshowski et al, or '815 are relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate the composition as taught by '548 at a pH as recited by instant claim 7, with a reasonable expectation of success, because Hoshowski, '046, or '815 teach formulating similar shampoo compositions at a pH as recited by instant claim 7.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/743836 and claims 1-10 of 11/245071. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 of copending Application No. 10/743836 and claims 1-10 of 11/245071.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because claims 1-9 of copending Application No. 10/743836 and claims 1-10 of 11/245071 of suggest a composition containing an amphiphatic amide lipid, a mixture of alkyl ether sulfate surfactants, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas McGinty can be reached on (571) 272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregory R. Del Cotto
Primary Examiner
Art Unit 1751

GRD
September 19, 2006